General

Guideline Title

Biopsy of a suspicious pigmented lesion.

Bibliographic Source(s)

Alberta Provincial Cutaneous Tumour Team. Biopsy of a suspicious pigmented lesion. Edmonton (Alberta): CancerControl Alberta; 2013 Feb. 7 p. (Clinical practice guideline; no. CU-006). [7 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Alberta Provincial Cutaneous Tumour Team. Biopsy of a suspicious pigmented lesion. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2012 Mar. 3 p. (Clinical practice guideline; no. CU-006).

Recommendations

Major Recommendations

- Excisional biopsy (elliptical, punch, saucerization) is preferred for small lesions. For larger lesions or lesions in cosmetically sensitive area, a punch or small incisional biopsy is preferred. Avoid wider margins to permit accurate subsequent lymphatic mapping (National Comprehensive Cancer Network [NCCN], 2012).
- Full thickness incisional or punch biopsy may be acceptable in large lesions or lesions in anatomically sensitive areas (e.g., palm/sole, digit, face, ear) or for very large lesions. Note: if clinical evaluation of incisional biopsy suggests that microstaging is inadequate, consider narrow margin excision (NCCN, 2012).
- Where invasive melanoma is suspected, shave biopsy may compromise pathological diagnosis and complete assessment of Breslow thickness.*
- Biopsy should be read by a pathologist experienced in pigmented lesions and should include the following elements (College of American Pathologists [CAP], 2011):
    - Breslow thickness (specify mm, indeterminate)
    - Ulceration (present, not identified, indeterminate)
    - Clark level
    - Microscopic satellitosis (not identified, present, indeterminate)
    - Macroscopic pigmentation (optional; not identified, present, present, patchy/focal, indeterminate)
    - Mitotic rate (less than 1 per mm^2 or specify number per mm^2)
    - Peripheral and deep margin status of biopsy (cannot be assessed, uninvolved by invasive melanoma, involved by invasive melanoma,

uninvolved by melanoma in situ, involved by melanoma in situ)
- Specimen laterality (right, left, midline, not specified)
- Tumour site
- Tumour size
- Tumour regression (not identified, present involving less than 75% of lesion, present involving 75% or more of lesion, indeterminate)
- Histologic sub-type (melanoma not otherwise classified, superficial spreading melanoma, nodular melanoma, lentigo maligna melanoma, acral-lentiginous melanoma, desmoplastic and/or desmoplastic neurotropic melanoma, melanoma arising from blue nevus, melanoma arising in a giant congenital nevus, melanoma of childhood, nevoid melanoma, persistent melanoma, other)
- Tumour infiltrating lymphocytes (optional; not identified, present non-brisk, present brisk)
- Growth phase (optional; radical, vertical, indeterminate)
- Lymph-vascular invasion (not identified, present, indeterminate)
- Perineural invasion (optional; not identified, present, indeterminate)

*For lesions in a cosmetically sensitive area, for which there is a low suspicion of melanoma (i.e., lentigo maligna, melanoma in situ), a broad shave biopsy of the thickest area may be acceptable (NCCN, 2012).

Clinical Algorithm(s)

An algorithm titled "Algorithm for the Management of Melanoma Stage 0" is available from the Alberta Health Services Web site .

Scope

Disease/Condition(s)

Mole or lesion that is suspicious for melanoma

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Dermatology

Oncology

Pathology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To describe the preferred biopsy techniques for patients presenting with a mole or lesion that is suspicious for melanoma, as well as to outline the appropriate reporting elements

Target Population

Adults over the age of 18 years with melanoma

Note: Different principles may apply to pediatric patients.

Interventions and Practices Considered

1. Excisional biopsy (elliptical, punch, saucerization) for small lesions
2. Punch or small incisional biopsy for larger lesions or lesions in cosmetically sensitive areas
3. Full thickness incisional or punch biopsy for large lesions or lesions in anatomically sensitive areas (e.g., palm/sole, digit, face, ear) or for very large lesions
4. Shave biopsy for lesions in a cosmetically sensitive area, for which there is a low suspicion of melanoma (i.e., lentigo maligna, melanoma in situ)
5. Reading of biopsy by experienced pathologist

Major Outcomes Considered

- Accuracy of diagnosis based on biopsy
- Adverse outcome based on misdiagnosis

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (Patient or Population, Intervention, Comparisons, Outcomes).

Guideline Questions

- What types of biopsy are appropriate for diagnosing a suspicious lesion in melanoma?
- What elements should be collected from the biopsy?

Search Strategy

The MEDLINE (1966 through January 2011), CINAHL, Cochrane, American Society of Clinical Oncology (ASCO) Abstracts and proceedings, and CANCERLIT databases were searched. The search included practice guidelines, systematic reviews, meta-analyses, randomized controlled trials, and clinical trials. Search terms included: suspicious pigmented lesion, pigmented lesion, or lesion and malignant melanoma and biopsy.

For the 2013 update of the guideline, PubMed was searched for evidence on biopsy techniques for cutaneous melanoma. The search term

"melanoma" was used and results were limited to clinical trials, published between January 2012 and January 2013. Citations were hand-searched for studies pertaining to biopsy techniques.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Cutaneous Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument (http://www.agreetrust.org) and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulated the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline

recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

Following a review of the evidence by the Alberta Provincial Cutaneous Tumour Team, no major changes to the recommendations were made.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Cutaneous Tumour Team.

When the draft guideline document has been completed, revised, and reviewed by the Knowledge Management (KM) Specialist and the working group members, it is sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized. Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

Evidence Supporting the Recommendations

References Supporting the Recommendations

College of American Pathologists (CAP). Protocol for the examination of specimens from patients with melanoma of the skin. Version 3.1.0.0. Northfield (IL): College of American Pathologists (CAP); 2011 Feb 1. 18 p.

National Comprehensive Cancer Network (NCCN). Melanoma guidelines, v.1.2012. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2012.

Type of Evidence Supporting the Recommendations

The recommendations are partially supported by existing guidance.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and staging of a suspicious lesion for the purposes of predicting prognosis and determining the best future management options

Potential Harms

Adverse outcomes of biopsy (histopathological misdiagnosis, inaccurate microstaging of tumour)

Qualifying Statements

Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Cutaneous Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

Implementation of the Guideline

Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of CancerControl Alberta.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Mar (revised 2013 Feb)

Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

CancerControl Alberta

There was no direct industry involvement in the development or dissemination of this guideline.

Guideline Committee

Alberta Provincial Cutaneous Tumour Team

Composition of Group That Authored the Guideline

Members of the Alberta Provincial Cutaneous Tumour Team include medical oncologists, radiation oncologists, surgical oncologists, dermatologists, nurses, pathologists, and pharmacists.

Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Cutaneous Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. CancerControl Alberta recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Cutaneous Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): CancerControl Alberta; 2013 Jan. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 11, 2012. The information was verified by the guideline developer on January 23, 2013. This summary was updated by ECRI Institute on April 28, 2014. The updated information was verified by the guideline developer on May 22, 2014.

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